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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

DARYL ROBERTS, INDIVIDUALLY AND AS
ADMINISTRATOR AD PROSEQUENDUM
FOR THE ESTATE OF CHERYL ROBERTS,

Plaintiff,

v.

ALARIS HEALTH, LLC, ALARIS HEALTH at
HAMILTON PARK, AND JOHN DOES 1-10,

Defendants.

Civil Action No.:

**NOTICE OF REMOVAL OF CIVIL ACTION
PURSUANT TO 28 U.S.C. §§ 1441 and 1446**

TO: Clerk of Court
United States District Court for the District of New Jersey
Martin Luther King Building & U.S. Courthouse
50 Walnut Street
Newark, NJ 07101

WITH NOTICE TO:

William C. Matsikoudis, Esq.
Matsikoudis & Fanciullo, LLC
128 Monticello Ave., STR 1
Jersey City, NJ 07304
Counsel for Plaintiff

PLEASE TAKE NOTICE THAT Defendants, Alaris Health at Hamilton Park and Alaris Health, LLC (“Defendants”), hereby removes to this District Court the state action currently

pending in the Hudson County Superior Court of New Jersey pursuant to 28 U.S.C. §§ 1441, 1446, and 42 U.S.C. §§ 247d-6d, 247d-6e (2020), for the reasons described more fully below.

PROCEDURAL HISTORY

1. This action was initially filed on or about March 17, 2022 in the Superior Court of the State of New Jersey – Hudson County, entitled DARYL ROBERTS, INDIVIDUALLY AND AS ADMINISTRATOR AD PROSESQUENDUM FOR THE ESTATE OF CHERYL ROBERTS as Docket No. HUD-L-000930-22. **See attached hereto as Exhibit A, a true and accurate copy of the Complaint filed on March 17, 2022.**
2. This case is removable under 28 U.S.C. § 1441(a) on the basis of “original jurisdiction” because Plaintiff’s Complaint asserts a claim “arising under” federal law within the meaning of 28 U.S.C. § 1331 by virtue of preemption under the Public Readiness and Emergency Preparedness (“PREP”) Act.

REMOVAL IS TIMELY

3. Defendants’ removal is timely under 28 U.S.C. § 1446(b) as it is being filed within 30 days after service on Defendants of a copy of the pleading from which it may be ascertained that the case is removable.
4. Concurrent with the filing of this Notice, Defendants are serving this Notice of Removal upon Plaintiff and filing a copy of this Notice of Removal with the Clerk of the Superior Court of the State of New Jersey – Hudson County pursuant to 28 U.S.C. § 1446(d). A Disclosure of Corporate Interests Form is also being filed, as is a complete copy of the State Court File.

INTRADISTRICT ASSIGNMENT

5. The United States District Court for the District of New Jersey embraces the district and division in which the Hudson County, New Jersey state court action is now pending, and thus this Court is a proper venue for the action pursuant to 28 U.S.C. § 110.

PLAINTIFF'S CLAIMS

6. Plaintiff's Complaint raises numerous allegations, including that Decedent Cheryl Roberts ("Decedent" or "Ms. Roberts") contracted and died from COVID-19 on or about April 5, 2020. Plaintiff alleges Ms. Roberts was employed as a Certified Nursing Assistant by Defendants when she contracted COVID-19 allegedly due to the manner in which Defendants used and administered COVID countermeasures, including sufficient PPE to staff. See generally Exhibit A at paras.7-24.
7. Plaintiff alleges intentional and willful misconduct claiming that Defendants are liable for "deliberately ignoring safety concerns raised by staff, refusing to provide PPE to staff and discouraging the use of PPE by staff." See Exhibit A at Count I, par. 28.
8. Count I of Plaintiff's Complaint specifically alleges an "intentional tort" and that Defendants "intentionally subject[ed] employees to substantially certain harm." See Exhibit A.
9. Defendants specifically deny each allegation contained in Plaintiff's Complaint, but acknowledge same for the purposes of filing the Petition for Removal herein.

I. JURISDICTION EXISTS UNDER 28 U.S.C. § 1331 (FEDERAL QUESTION)

10. This is a civil action over which the Court has original jurisdiction under 28 U.S.C. § 1331 and is one that may be removed to this Court pursuant to 28 U.S.C. § 1441 and 1446 based on federal question jurisdiction.

A. Plaintiff's State Law Cause of Actions are Completely Preempted by the PREP Act.

11. Complete preemption is an exception to the well-pleaded complaint rule. See Metro-Life Ins. Co. v. Taylor, 481 U.S. 58, 64–64 (1987).
12. Complete preemption occurs when the “pre-emptive force of a statute is so ‘extraordinary’ that it ‘converts an ordinary state common-law Complaint into one stating a federal claim for purposes of the well-pleaded Complaint rule.’” Caterpillar Inc. v. Williams, 482 U.S. 386, 393 (1987) (quotation omitted); Metro-Life, 481 U.S. at 63-64 (complete preemption exists when the preemptive force of federal law is so powerful that it displaces any state law cause of action and leaves room only for a federal claim for purposes of the “well-pleaded complaint” rule). Complete preemption “‘confers exclusive federal jurisdiction in certain instances where Congress intended the scope of a federal law to be so broad as to entirely replace any state-law claim.’” Marin General Hosp. v. Modesto & Empire Traction Co., 581 F.3d 941, 945 (9th Cir. 2009) (quoting Franciscan Skemp Healthcare, Inc. v. Cent. States Joint Bd. Health & Welfare Trust Fund, 538 F.3d 594, 596 (7th Cir. 2008)) (internal quotations omitted).
13. According to the Third Circuit, complete preemption exists when: (1) a statute contains civil enforcement provisions within the scope of which a plaintiff’s state law claims fall; and (2) there is a “clear indication of Congressional intention to permit removal despite the plaintiff’s exclusive reliance on state law.” Railway Labor Executives Ass’n v. Pittsburgh & Lake Erie R.R. Co., 858 F.2d 936, 942 (3rd Cir. 1988) (citing Franchise Tax Bd. of State of Calif. v. Construction Laborers Vacation Trust for Southern Calif., 463 U.S. 1, 24 (1983)).

14. The PREP Act is a complete preemption statute. As explained by the U.S. Department of Health and Human Services (“HHS”) in a January 2021 Advisory Opinion issued by the Secretary’s Office of General Counsel (“OGC”), the PREP Act is a complete preemption statute in that it establishes an exclusive federal remedy for claims falling thereunder.
15. Congress enacted the PREP Act in December 2005 to encourage and coordinate a thorough, rapid, and comprehensive response to declared public health emergencies by granting broad immunity to covered persons (like Defendants) for claims of loss related to the administration or use of covered countermeasures, so that they may combat the emergency without fear of litigation or liability. See 42 U.S.C. § 247d-6d(a)(1).
16. Specifically, the legislation empowers the Secretary of HHS to issue a written declaration and provide that a "covered person shall be immune from suit and liability under Federal and State law with respect to **all claims for loss** caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure" during a health emergency. 42 U.S.C. § 247d-6d(a)(1). The HHS Secretary’s declaration is controlling and cannot be reviewed. Indeed, the PREP Act provides that “[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.” 42 U.S.C. § 247d-6d(b)(7). By these explicit directives, and particularly by making the actions of the Secretary non-reviewable, Congress intended the Secretary’s declaration (including any amendments) to have the force of law.
17. In a subsection of the PREP Act conspicuously titled, “PREEMPTION OF STATE LAW,” Congress also provides, in relevant part, that "no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any

provision of law or legal requirement that is different from, or in in conflict with, any requirement applicable under this section" and relates to, among other things, use or administration of a covered countermeasure." 28 U.S.C. § 247d-6d(b)(8).

18. Under 42 U.S.C. § 247d-6d(d)(1), "the sole exception to the immunity from suit and liability of covered persons ... shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct."
19. For claims that do not assert "willful misconduct," the exclusive federal remedy for relief is established under §247d-6e, which permits an individual to claim no-fault benefits through the Covered Countermeasure Process Fund for a "covered injury directly caused by the administration or use of a covered countermeasure." State causes of action for claims relating to covered countermeasures are **impermissible**, as the PREP Act substitutes an exclusive federal cause of action and federal claims process in place of all state claims relating to the use and administration of covered countermeasures.
20. The PREP Act further sets forth the procedures for the federal suit that it creates. Pursuant to subsection (e)(1), titled "Exclusive Federal Jurisdiction," any action for willful misconduct must be filed in the U.S. District Court for the District of Columbia. Such claims are also subject to heightened pleading requirements (i.e., requirement that claims are to be plead with particularity) and verification of and submission of a physician declaration in support of the complaint; and are assigned to a three- judge panel which has jurisdiction to consider motions to dismiss and motions for summary judgment. 42 U.S.C. § 247d-6d(e)(1), (e)(3) (e)(4) and (e)(5). Moreover, pursuant to Section 247d-6d(e)(10),

The United States Court of Appeals for the District of Columbia Circuit shall have jurisdiction of an interlocutory appeal by a covered person taken within 30 days of an order denying a motion to dismiss or motion for summary judgment based on an assertion

for the immunity from suit conferred by subsection (a) or based on an assertion of the exclusion under subsection (c)(S). (Emphasis added).

21. Thus, the PREP Act creates an exclusive federal cause of action for the claims asserted by Plaintiff and the procedures and remedies governing that cause of action. It also establishes procedures for obtaining no-fault benefits through the Covered Countermeasure Process Fund, 42 U.S.C § 247d-6.

22. This exclusive two-part federal remedy forms the basis for complete preemption. Accordingly, where a cause of action falls within the scope of the PREP Act, the PREP Act completely preempts that cause of action and confers federal subject matter jurisdiction thereon. It does not matter whether the complaint expressly raises a federal claim or whether it even cites the completely preemptive statute. Rather, the doctrine of complete preemption “converts [plaintiffs’] ordinary state common law complaint into one stating a federal claim for purposes of the well-pleaded complaint rule.” Metro. Life, 481 U.S. at 65.

23. For the COVID-19 pandemic, the PREP Act was invoked on March 10, 2020, when the HHS Secretary issued a Declaration invoking the PREP Act. The Declaration was effective as of February 4, 2020. In the Declaration, the Secretary declared that "Administration of Covered Countermeasures means physical provision of the countermeasures to recipients, **or activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures.**" 85 Fed. Reg. 15198 (Mar. 17, 2020), *amended by* 85 Fed. Reg. 21012 (Apr. 15, 2020), 85 Fed. Reg. 35100

(June 8, 2020), 85 Fed. Reg. 52136 (Aug. 24, 2020), 85 Fed. Reg. 79190 (Dec. 9, 2020), 85 Fed. Reg. 7872 (February 2, 2021), 86 Fed. Reg. 9516 (February 16, 2021), 86 Fed. Reg. 14462 (Mar.16, 2021), 86 Fed. Reg. 41977 (Aug. 4, 2021), *and* 86 Fed. Reg. 51160 (Sept. 14, 2021) (*as corrected by* 86 Fed. Reg. 54696 (Oct. 4, 2021)) (herein, “the Declaration”).¹

24. On December 3, 2020, the Secretary issued a Fourth Amended Declaration under the PREP Act, effective as of February 4, 2020. The Secretary's Fourth Amended Declaration provides that **"COVID-19 is an unprecedented global challenge that requires a whole-of-nation response that utilizes federal, state, and local-distribution channels as well as private-distribution channels. Given the broad scale of this pandemic, the Secretary amends [Section VII of the Declaration to extend PREP Act coverage to additional private- distribution channels"** (Emphasis added).

25. The Fourth Amended Declaration specifically provides that Section VII of the Declaration is amended to extend liability protection under the PREP Act to Covered Persons for Recommended Activities that are related to: "Covered Countermeasures that are:

- a. Licensed, approved, cleared or authorized by the FDA (or that are permitted to be used under an Investigational New Drug Application or an Investigational Device Exemption) under the FD&C Act or PHS Act to treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom; or

¹ The Secretary subsequently issued an Amended Declaration under the PREP Act, which was effective as of March 27, 2020. The Amendment added respiratory protective devices approved by NIOSH (National Institute for Occupational Safety and Health) as a covered countermeasure under the PREP Act. On June 4, 2020, the Secretary further amended the March 10, 2020 Declaration to clarify that covered countermeasures under the Declaration include qualified products that limit the harm COVID-19 might otherwise cause. This Amendment was effective as of February 4, 2020. 85 FR 21012. Throughout the pandemic, HHS has reinforced the complete preemptive effect and the broad scope of the PREP Act in its Advisory Opinions and Amendments to the Declaration. To date, the Declaration has been amended nine (9) times, five (5) of which have been under the Biden Administration, further confirming the expansive breadth of the Act and its preemptive effect.

- b. A respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be priority for use during a public health emergency declared under section 319 of the PHS Act to prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom."

85 Fed. Reg. 79194, 79196-97²

26. The Fourth Amended Declaration further makes explicit that there can be situations where a decision ***not*** to administer a Covered Countermeasure to a particular individual can equate to the administration of a countermeasure to an individual under the PREP Act. For example, "[p]rioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority's directive, can fall within the PREP Act and this Declaration's liability protections." Fed. Reg. 79194, 79197 (emphasis added).

27. Additionally, the Fourth Amended Declaration provides that the **Declaration must be construed in accordance with the HHS Office of the General Counsel (OGC) Advisory Opinions on the Public Readiness and Emergency Preparedness Act and the Declaration ("Advisory Opinions")**. Thus, the Fourth Amended Declaration incorporates all Advisory Opinions related to COVID-19 and the PREP Act into the

² Moreover, attached as Appendix A to the Advisory Opinion is a list of the "covered countermeasures" for which emergency use authorizations have been issued by the United States Food and Drug Administration. The list includes twelve pages of **COVID-19 test kits**, and provides that face shields, gowns, shoe covers, non-surgical isolation gowns, surgical caps, properly labeled non-surgical masks, and certain non-NIOSH approved respirators are covered by an EUA. Surgical masks are not listed; however, such masks are Class II medical devices which are cleared by the FDA for use. (See 21 CFR 878.4040). Thus, **COVID-19 testing kits**, face masks, gowns, gloves and other PPE are "qualified pandemic or epidemic products" and "covered countermeasures" under the PREP Act, as such products are either FDA cleared/approved or are included in an EUA.

Secretary's March 10, 2020 initiating Declaration, affording them controlling weight. 85 Fed. Reg. 79192, 79194-95.³

28. On January 8, 2021, the HHS Secretary's Office of the General Counsel issued Advisory Opinion 21-01 ("AO 21-01") which further confirms that the PREP Act can be triggered even in cases of non-use of covered countermeasures when the non-use is the result of a conscious decision. This includes, as just one example, prioritization or purposeful allocation of a countermeasure and "particularly if done in accordance with a public health authority's directive." According to the opinion, the view that the PREP Act does not encompass alleged omissions to use of covered countermeasures "clashes with the plain language of the PREP Act, which extends immunity to anything 'relating to' the administration of a covered countermeasure. In the opinion, HHS further indicates that **the PREP Act is triggered in cases where a plaintiff alleges a failure to use PPE, if the failure was the outcome of some form of decision-making process.**

29. AO 21-01 also provides that the PREP Act is a **complete preemption** statute in that the "sine qua non of a statute that completely preemption is that it established either a federal cause of action, administrative or judicial, as the only viable claim or vests exclusive jurisdiction in a federal court. The PREP Act does both."

30. The Fifth Amendment to the Declaration issued on February 2, 2021 reiterated that "[t]he plain language of the PREP Act makes clear that there is a complete preemption of state law." Fifth Amendment to the Declaration Under the Public Readiness and Emergency

³ Section (b)(7) of the PREP Act provides that "[n]o court of the United States, or of any state, shall have subject jurisdiction to review whether by mandamus or otherwise, any action by the Secretary under this subsection." (emphasis added). Also, where Congress has expressly delegated interpretive authority to an agency, that agency's interpretative proclamations are controlling on federal courts. See Chevron USA, Inc. v. Natural Resource Defense Council, Inc., 467 US 837, 843-844 (1984).

Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 86 Fed. Reg. 7872, 7874 (Feb. 2, 2021).

31. The United States concurs with this position. In filing a Statement of Interest in Bolton v. Gallatin Center for Rehabilitation & Healing, LLC, the United States likewise asserts **the PREP Act is a complete preemption statute** with respect to the administration or use of covered countermeasures. **"Two key provisions of the PREP Act operate together to demonstrate its completely preemptive nature: the immunity provision and the exclusive alternative remedy provision."** See attached hereto as Exhibit B, a true and accurate copy of the Statement of Interest filed in Bolton v. Gallatin Center for Rehabilitation & Healing, LLC, Case 3:20-cv-00683 (M.D. Tenn.)
32. A number of other statutes that are similar to the PREP Act also have been held to establish complete preemption and original federal jurisdiction, such as the Labor Management Relations Act ("LMRA"),⁴ the Employee Retirement Income Security Act ("ERISA"),⁵ the

⁴ Any state law claims that are substantially dependent on analysis of a collective-bargaining agreement are completely preempted by section 301 of the LMRA and must be brought in federal court. Caterpillar Inc. v. Williams, 482 U.S. 386, 393 (1987). However, before an employee may bring a Section 301 claim in court, the employee must "at least *attempt to exhaust exclusive grievance and arbitration procedures* established by the [collective] bargaining agreement." Campbell v. Kane, Kessler, P.C., 144 F. App'x 127, 130 (2d Cir. 2005) (quotation omitted) (Emphasis added.)

⁵ ERISA is another complete preemption statute that has a "firmly established federal policy favoring exhaustion of administrative remedies" for purposes of, *inter alia*, reducing the number of frivolous lawsuits, providing a non-adversarial method of claims settlement and minimizing the costs of claims settlement for all. Kennedy v. Empire Blue Cross & Blue Shield, 989 F.2d 588, 594 (2d Cir. 1993); Paese v. Hartford Life & Acc. Ins. Co., 449 F.3d 435, 445 (2d Cir. 2006).

Federal Tort Claims Act ("FTCA"),⁶ and the Air Transportation Safety and System Stability Act ("ATSSSA").⁷

33. Additionally, several courts have found the PREP Act to be completely preemptive. In Rachal v. Natchitoches Nursing & Rehabilitation Center, LLC, the Court held that the PREP Act is a complete preemption statute and that it “*exclusively encompass[es]* claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.” Rachal v. Natchitoches Nursing & Rehabilitation Center, LLC, No. 1:21-cv-334 at n.3 (W.D. La. Apr. 30, 2021). See also Reilly v. Delta Healthcare II, LLC, No. 8:21-cv-1013-JSM-JSS (M.D. Fla June 7, 2021); Branch v. Lilac Holdings, LLC, No. 21-cv-00605-BAS-MDD (S.D. Cal. June 16, 2021) (both conceding applicability of PREP Act in granting defendants’ motions to dismiss based on immunities and other protections under the Act).
34. In Garcia v. Welltower OpCo Group, the Court also held that the PREP Act provides for complete preemption in that “allegations of use and misuse” of covered countermeasures fall within the purview of, and are completely preempted by, the PREP Act. Garcia v. Welltower OpCo Group, 2021 WL 492581, at *7, *21 (C.D. Cal. Feb. 10, 2021).

⁶ The FTCA, which is strikingly similar to the PREP Act, immunizes certain persons from liability and also provides an administrative/judicial remedial scheme for claims falling thereunder. The FTCA affords liability protection to federal employees for any negligent or wrongful acts committed while acting within the scope of their employment, and provides an exclusive federal cause of action in the federal district courts against the United States under specified circumstances. Like the PREP Act, before a judicial action may be instituted, the claimant must first present the claim before the appropriate federal agency for adjudication. 28 U.S.C. § 2675. This jurisdictional requirement cannot be waived, Celestine v. Mount Vernon Neighborhood Health Ctr., 403 F.3d 76, 82 (2d Cir. 2005), resulting in the dismissal of claims where a claimant fails to exhaust the administrative remedies.

⁷ Congress passed the ATSSSA after the September 11th terrorist attacks to create an exclusive federal cause of action for damages “arising out of the hijacking and subsequent crashes” of the aircraft used in the attacks. ATSSSA § 408(b)(1), 49 U.S.C. § 40101. Like the PREP Act, the ATSSSA also includes a victim’s compensation fund. Similar to the PREP Act, Congress’ principal goals in enacting the ATSSSA “were to provide relief *without litigation* to individuals harmed as a result of the crashes and to *limit the liability of entities* that were likely to be sued for injuries suffered in connection with the crashes.” In re WTC Disaster Site, 414 F.3d 352, 377 (2d Cir. 2005) (Emphasis added).

35. In Parker v. St. Lawrence Co. Pub. Health Dept., 102 A.D. 3d 140, 954 N.Y.S.2d at 262 (2012), the court held that the narrower H1N1 Declaration issued pursuant to the PREP Act warranted an exclusive federal forum and further held that state courts have no jurisdiction to hear claims arising out, or concerning, a declaration issued pursuant to the PREP Act.

36. And recently, the Third Circuit Court of Appeals concluded in Maglioli v. Alliance Holdings LLC d/b/a Andover Subacute & Rehabilitation I, et al., (Nos. 20-2833 & 20-2834) (3rd Cir., October 20, 2021), held that the PREP Act is a complete preemption statute when **willful misconduct is alleged**. According to the Court, the PREP Act “unambiguously” creates an exclusive cause of action for willful misconduct thereby establishing original federal jurisdiction over such claims allowing removal jurisdiction under 28 U.S.C. §§ 1331 and 1442. Maglioli at *7 (citing 42 U.S.C. §§ 247d-6d, 247d-6e).

37. Also, while removing Defendants respectfully assert that the PREP Act completely preempts all claims arising from or relating to the use of a covered countermeasure even beyond those of willful misconduct, the issue is moot here as the Complaint unequivocally alleges willful and intentional misconduct in allegedly causing injuries to Plaintiff Decedent, implicating the PREP Act and warranting federal rather than state jurisdiction. See Exhibit A at Count I. Plaintiff’s claims for willful misconduct unquestionably bring them under the PREP Act and invoke Article III jurisdiction and 28 U.S.C. §1331, 1441. “Congress said the cause of action for willful misconduct is exclusive, so it is.” Maglioli at *9.

B. The PREP Act Applies to Plaintiff's Claims

1. Defendants are a Covered Person Under the Statute

38. The PREP Act applies to “covered persons” who administer or use a “covered countermeasure” during a “recommended activity” in relation to COVID-19. 42 U.S.C. § 247d-6d.

39. Pursuant to the Act, a “covered person” includes (i) the United States; (ii) manufacturers and distributors of covered countermeasures; (iii) program planners; and (iv) qualified persons who prescribe, administer, or dispense covered countermeasures. 42 U.S.C. § 247d-6d(i)(2).

40. “Qualified persons” include licensed health professionals and other individuals authorized to prescribe, administer, or dispense covered countermeasures under state law, as well as other persons identified in a declaration by the Secretary. 42 U.S.C. § 247d-6d(i)(8).

41. “Program planners” include state and local governments or other persons who supervise or administer programs that dispense, distribute, or administer covered countermeasures, *or* provide policy guidance, facilities, and scientific advice on the administration or use of such countermeasures. 42 U.S.C. § 247d-6d(i)(6).

42. The meaning of “program planner” and “qualified person” has been clarified as follows:

...State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with [the Secretary's declaration].

42 U.S.C. § 247d-6d[i][6].

43. Under the Secretary’s declaration, “[A] **private sector employer or community group or other ‘person’ can be a program planner when it carries out the described activities.**”

85 Fed. Reg. at 15,202.

44. Furthermore, on August 14, 2020, the HHS Secretary’s Office of General Counsel confirmed that senior living communities are “covered persons” subject to immunity under the PREP Act as “program planners” and “qualified persons.” [OGC Letter to Thomas Barker.] The Office of General Counsel also published a Guidance confirming that COVID testing in nursing homes is a covered countermeasure triggering the Act.⁸

45. On October 23, 2020, the HHS Office of the General Counsel’s Advisory Opinion No. 20-04 (“AO 20-04”) verified that the term “program planner” is broadly defined.⁹ The opinion also explained that PREP Act coverage will apply to a covered person using a covered countermeasure in accordance with any public health guidance from an “Authority Having Jurisdiction.”

46. The January 8, 2021 AO 21-01 more broadly outlined that a “program planner” under the Act is “someone who is involved in providing or allocating covered countermeasures,” and that “program planning inherently involves the allocation of resources.” The Advisory Opinion thereby concluded that **“decision-making that leads to the non-use of covered countermeasures by certain individuals is the grist of program planning and is expressly covered by [the] PREP Act.”**

⁸ HHS, Office of the General Counsel, Letter to Thomas Barker, Foley Hoag LLP (Aug. 14, 2020) *available at* <https://www.govinfo.gov/content/pkg/FR-2020-08-24/pdf/2020-18542.pdf> [Aug. 31, 2020].

⁹ HHS, Office of the General Counsel, “Advisory Opinion No. 20-04 on the Public Readiness and Emergency Preparedness Act and the Secretary’s Declaration Under the Act” (Oct. 22, 2020, as modified Oct. 23, 2020), *available at* (https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO%204.2_Updated_FINAL_SIGNED_10.23.20.pdf) [Advisory Opinion 20-04.]

47. Defendant facility qualifies as a “covered person” under the PREP Act. During the time set forth in the underlying Complaint, Defendant facility acted as both a “qualified person” and a “program planner” in that Defendant facility operated as a skilled nursing facility licensed by the New Jersey Department of Health.
48. Defendant facility employed various medical professionals including administrators, directors, nursing personnel, physicians, therapists, and nursing aides who were authorized to allocate, administer, prescribe, and dispense the covered countermeasures set forth in Plaintiff’s Complaint, including PPE such as facemasks, gloves, gowns, face shields, N95 masks, COVID testing materials, thermometers, and other items which qualify as pandemic or epidemic products). Additionally, these individuals developed, administered, and oversaw policies, procedures, and programs related to infection control.
49. During the timeframe relevant to Plaintiff’s Complaint, there was scarcity of PPE and COVID-19 testing kits and resources (85 Fed. 17592- Notice of Designation of Scarce Material, and <https://www.bloomberg.com/news/articles/2020-04-07/coronavirus-testing-accuracy-and-availability-shortages-remain>). Defendant facility was a “program planner” since it supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a qualified pandemic or epidemic product, which included decisions pertaining to the allocation and administration of covered countermeasures such as PPE, testing, etc. including how best to optimize supplies and when use was appropriate. Defendant facility’s actions with respect to the coordination and implementation of infection control programs thus inherently involved conscious decision making including, but not limited to the **prioritization** and purposeful allocation of covered countermeasures including PPE.

50. Defendant facility was a “program planner” since it supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a qualified pandemic or epidemic product, which included decisions pertaining to the allocation and administration of covered countermeasures such as testing, PPE, etc. and how best to optimize supplies especially in view of the nationwide scarcity of testing and PPE during the relevant time period. Defendant facility’s actions with respect to the coordination and implementation of infection control programs thus inherently involved conscious decision making including, but not limited to the **prioritization** and purposeful allocation of covered countermeasures including when and how best to administer COVID-19 testing kits and when to discharge residents to maximize beds available in medical facilities.

51. The decisions with respect to resource allocation, infection prevention protocols and decisions go directly to the heart of Plaintiff’s Complaint insofar as decisions regarding how and when to use, distribute, and allocation PPE were made to preserve globally scarce PPE and other COVID countermeasures.

52. This matter does not involve nonfeasance or total inaction but instead relates to the propriety of the countermeasures and infection control programs and the manner in which they were implemented by Defendant facility, including and especially those pertaining to COVID-19 testing, PPE, and preservation of PPE in connection with the direct treatment of patients, thereby implicating the PREP Act.

2. Plaintiff’s Claims Arise from Defendants’ Use and Administration of “Covered Countermeasures.”

53. The PREP Act is applicable with respect to a “covered countermeasure” which is as: “(1) a qualified pandemic or epidemic product (as defined in § 247d-6d (i)(7)) . . . or (4) a respiratory protective device that is approved by the National Institute for Occupational

Safety and Health (“NIOSH”) and that the Health and Human Service Secretary determines to be a priority for use during a public health emergency declared under section 247d.” 42 U.S.C. § 247d-6d(i)(1). A “qualified pandemic or epidemic product” is defined as: a drug, biologic product or device that is:

“(A)(i) a product manufactured, used, designed, developed, modified, licensed, or procured—

- (I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or
- (II) to limit the harm such pandemic or epidemic might otherwise cause;
- (ii) a product, manufacture, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious of life-threatening disease or condition caused by a product described in clause (i); or
- (iii) a product or technology intended to enhance the use or effect of a drug, biologic product, or device described in clause (i) or (ii); and
- (B)(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 262 of this title;
- (ii) the object of research for possible use as described in subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act; or
- (iii) **authorized for emergency use** in accordance with section 564, 564A, or 564B of the Federal Food, Drug and Cosmetic Act.”

See 42 U.S.C. § 247d-6d(i)(7).

54. The March 17, 2020 Declaration expanded the categories of “covered countermeasures” eligible for immunity to include **any** device used to treat, diagnose, cure, prevent or mitigate COVID-19 or its spread. The Declaration was subsequently amended to add respiratory protective devices like COVID tests to the list of covered countermeasures. See 42 U.S.C. § 247d-6d(i)(1)(D); see also 85 Fed. Reg. at 21,014.

55. On June 8, 2020, the Declaration was amended again to reflect the HHS’s original intent to “identify the full range of qualified countermeasures” as permitted under the PREP Act. 85 Fed. Reg. 35100. Thus, a covered countermeasure includes a broad range of products and devices specified as: (i) a qualified pandemic or epidemic product; (ii) a security

countermeasure; (iii) a drug, biological product, or device that the U.S. Food and Drug Administration (FDA) has authorized for emergency use; and, (iv) a NIOSH-approved respiratory protective device.

56. A "biological product" is "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(i); see also id. §§ 247d-6b(c)(1)(B), 247d-6d(i)(7).

57. Plaintiff's claims related to such countermeasures including PPE such as facemasks, gloves, gowns, face shields, N95 masks, COVID testing materials, thermometers, and other items which qualify as pandemic or epidemic products under the PREP Act. Exhibit A at Count I, paras. 7-24.

3. There is a Causal Nexus between the Administration or Use of a Covered Countermeasure and the Claims of Loss

58. The PREP Act "applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the . . . distribution . . . **purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.**" 42 U.S.C. § 247d-6d (a)(2)(B)

59. While the term "administration" is undefined in the PREP Act, the March 17, 2020 Declaration explained that "Administration of a Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and **decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management**

and operation of locations for purpose of distributing and dispensing countermeasures.” 85 Fed. Reg. at 15,200. Thus, the definition of “administration” extends not only to the physical provision of countermeasures to recipients, such as vaccinations, but also **“to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities.”** Id.

60. Significantly, Maglioli confirms that the Secretary of HHS has broad and extensive non-reviewable authority for all substantive applications of the PREP Act, as bestowed on him by Congress. Maglioli at *8. Specifically, the Third Circuit Court reiterated that “the Secretary controls the scope of immunity through the declaration and amendments, within the confines of the PREP Act.” The Secretary defines those “acts and omissions” that fall under the Act. Maglioli at *6.

61. The Office of the Secretary has confirmed -- including in AO 21-01 -- that the PREP Act is triggered even in instances involving non-use or the non-administration of a covered countermeasure. The Advisory Opinion specifically notes “[p]rioritization of purposeful allocations of a Covered Countermeasure, particularly if done in accordance with a public health authority’s directive, can fall within the PREP Act.” Furthermore, “a conscious decision not to use a covered countermeasure could relate to the administration of the countermeasure.”

62. AO 21-01 further clarifies that the PREP Act would still be triggered when a facility “fails to administer [a] therapeutic...assuming the non-use of the therapeutic was the result of conscious decision-making.” However, if a plaintiff alleges that the decisions surrounding

the use of a therapeutic were “wanton and willful,” those matters **must** be transferred to the District Court of the District of Columbia for resolution by a three-judge panel. See 42 U.S.C. 247d-6d)d)-(e).

63. The Advisory Opinion further clarifies that the PREP Act should be applied to the broadest extent possible, and even in rare instances where a plaintiff argues that “defendant failed to make any decisions whatsoever,” federal courts are “**free to entertain discovery to ascertain, for jurisdictional purposes, the facts underlying the complaint.**” (citing United Surgical Assistants, LLC v. Aetna Life Ins. Co., 2014 WL 4059889 at *1 (M.D. Fla. Aug. 14, 2014)).

64. In the present matter, Plaintiff’s Complaint on its face alleges claims arising from the manner in which the Alaris facility administered and allocated PPE and other countermeasures to individuals within the facility, including staff and residents. It is therefore clear that Defendant facility made conscious allocation and administration decisions regarding its efforts to prevent the spread of COVID-19. The actions taken by Defendant facility in this matter are precisely the types of actions -- administration and use of countermeasures -- which fall under and are to be given “sweeping” protections under the PREP Act.

WHEREFORE, Defendants hereby notify Plaintiff that the above-entitled action, formerly pending in the Hudson County Superior Court, has been removed from that state court to this Federal Court. Should any question arise as to the propriety of this removal, Defendants respectfully request an opportunity to provide further briefing and oral argument.

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Date: April 20, 2022